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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,558	07/13/2005	Richard Frank Tester	08830-0307US1	2680

23973 7590 02/20/2009

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EXAMINER	
PALENIK, JEFFREY T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
02/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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In re Application of	:
Tester et al	:Decision on Petition
Serial No.: 10/517,558	:
Filed : 13 July 2005	:
Attorney Docket No.: 08830-0307US1	:

This letter is in response to the Petition under 37 C.F.R. 1.144 and 1.181 filed on 23 January 2009 requesting reconsideration of the lack of unity requirement mailed 27 October 2007.

BACKGROUND

This application was filed as a national stage of a PCT application and as such is entitled to PCT unity of invention rules.

On 27 October 2007, the examiner set forth a lack of unity requirement which divided the claims 1-12, 16-19, 23 and 25-35 into 4 groups as follows:

> Group I, 1-12, 16, 23 and 25 drawn to a bioadhesive pharmaceutical formulation comprising beta-limit dextrin
> Group II, Claims 17-19 drawn to nutritional product comprising beta-limit dextrin
> Group III, claims 26-29 drawn to a method of delivering an active agent formulation comprising beta-limit dextrin
> Group IV, claims 30-35 drawn to a method of providing nutrition containing beta-limit dextrin

The examiner also required an election of species between buccal-melt, aerosol powder or thin film.

On 28 February 2008, applicants elected Group I, claims 1-12, 16, 23 and 25 and species (i) buccal-melt product with traverse. Applicants added new claims 36 and 37.

On 19 August 2008, the examiner considered the traversal and made the lack of unity determination FINAL. On the form PTOL-326, the examiner accounted for the claims as follows:

> Claims 1-12, 16, 23 and 25 are pending.
> Claim 6 is withdrawn from consideration.
> Claims 1-5, 7-12, 16, 23 and 25 are rejected.

In the body of the Office action, the examiner accounted for the claims as follows:

> Claims 6, 36 and 37 are withdrawn from consideration.
> Claims 4 and 5 were rejected under 35 U.S.C. 112, 2nd paragraph.
> Claims 1-5, 7-12, 16, 23 and 25 were rejected under 35 U.S.C. 103(a).

On 23 January 2009, applicants filed a response to the Office action and this petition.

DISCUSSION

The file history and petition have been considered carefully.

Before turning to the merits of the petition, it is noted that the status of the claims in Office action mailed 19 August 2008 is inconsistent and incomplete in the PTOL 326 form and in the body of the Office action. Claims 17-19 and 26-37 are also pending and have been presumably withdrawn from consideration as being directed to non-elected inventions.

Turning now to the merits of the petition, PCT Rules 13.2 states that:

> **Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.**

A. Concerning the Lack of Unity Requirement Made between Group I (product) and Group III (process of using the product):

To show unity of invention lacking amongst the first product and the method of using the first product, applicants are correct that the examiner would need to address the technical feature shared by the product of Group I and the process of Group III. In this instance, the shared technical feature is the product of claim 1.

Chapter 10 of the ISPE Guidelines makes it clear that the contribution must be both in terms of novelty, which corresponds to anticipation under US practice, and inventive step, which corresponds to unobviousness under US practice. The criteria for determining the concept of "contribution over the prior art" is further discussed in Chapter 10 of the International Search and Preliminary Examination Guidelines:

Rule 13.2; AI Annex B, Part 1(b)

> 10.02 Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," is considered with respect to novelty and inventive step. For example, a document discovered in the international search shows that there is a presumption of lack of novelty or inventive step in a main claim, so that there may be no technical relationship left over the prior art among the claimed inventions involving one or more of the same or corresponding special technical features, leaving two or more dependent claims without a single general inventive concept.

The examiner originally supported the lack of unity of invention determination with respect both to the Groupings with the following reasons:

> **The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: there is no special technical feature since U.S. Patent 4,780,149, teaches the application of β-limit dextrin containing starch hydrosylates via food and pharmaceutical products (column 1, lines 6-9).**

While the original reference used by the examiner to demonstrate that unity was lacking did not address all the limitations of claim 1, the rejection of the product claims of elected Group I under 35 USC 103 is now provided as evidence that the invention as claimed does not make a contribution over the prior art. Because the product of Group I does not make a contribution over the prior art, unity of invention is lacking between Group I and Group III.

Should all claims to the elected product of Group I become in condition for allowance, MPEP 1893.05(d) provides the following guidance on rejoinder practice for applicants filed in compliance with 35 U.S.C 371.

> If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04. Any nonelected processes of making and/or using an allowable product should be considered for rejoinder. The examiner should notify applicants of potential rejoinder of non-elected process claims by placing form paragraph 8.21.04 at the end of any lack of unity determination made between a product and a process of making the product or between a product and a process of using the product.

Concerning the Election of Species Requirement Between buccal-melt and thin film.

The election of species requirement supported using the same rationale set forth the following species: (i) buccal-melt, (ii) aerosol powder and (iii) thin film. The relevant claims are set forth below:

4. (Currently amended) A bioadhesive pharmaceutical formulation as claimed in Claim 1 which is a buccal-melt ~~type~~ product.

5. (Original) A bioadhesive pharmaceutical formulation as claimed in Claim 4 which is a wafer.

6. (Previously presented) A bioadhesive pharmaceutical formulation as claimed in Claim 1 which is a powder for use in aerosol delivery formulations.

7. (Previously presented) A bioadhesive pharmaceutical formulation as claimed in Claim 1 which is a thin film.

Applicants elected buccal-melt. The examiner made the lack of unity determination FINAL in the Office action mailed 19 August 2008.

However, in that same Office action on the merits, the examiner examined claim 7 directed to the non-elected species of thin film along with claims to the elected species of buccal-melt. The examiner rejected all of claims 1-5, 7-12, 16, 23 and 25 under 35 U.S.C. 103(a) as being unpatentable over Kaper et al and Burgoyne et al. In the body of the obviousness rejection, the examiner has considered the merits of withdrawn species of thin film (claim 7) by stating that, "the Examiner broadly and reasonably interprets a wafer as being a form of or species of thin film." The examiner went on to state that "bucally (e.g., orally) administered compositions which are very well known in the art as having many different form, particularly a wafer or a ribbon form, as evidence by Garbutt..."

Because the term "wafer" (claim 5) encompasses or is encompassed by "thin film" (claim 7), because both wafers and thin films may be administered to melt in the mouth (buccal-melt type product of claim 4), and because the Office action addressed claims 4, 5 and 7 (directed to buccal-melt-type product, wafer and thin film, respectively) on the merits, the election of species requirement amongst the "species" of buccal-melt and thin film cannot be maintained.

Concerning the Withdrawal of newly added Claim 36, directed to lyophilized products:

On 28 February 2008, applicants added new product claim 36 shown below:

36. (Previously presented) A bioadhesive pharmaceutical formulation according to claim 1, wherein said formulation is a lyophilized formulation.

In the Office action mailed 19 August 2008, Claim 36 was withdrawn from consideration. The examiner accounted for withdrawing claim 36 from consideration by stating that had the claim been submitted with the previous revision of the claims, the freeze-dried formulation of claim 36 would also have been subjected to the same election of species requirement as the buccal-melt product and aerosol powder formulations. Then the examiner pointed to page 14, lines 21-27 of the specification stating that freeze-dried matrix formulations are independent from both wafer and powder forms.

It is noted that "independence" is not a criteria for finding unity of invention lacking under PCT Guidelines. Unity of invention is lacking between elected species and the withdrawn species of claim 36 for the reasons set forth below:

> Newly submitted claim 36 is directed to an invention that lacks unity with the invention originally claimed for the following reasons: Claim 36 is directed to the non-elected species of lyophilized formulation. This species lacks unity of invention with the elected species because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.
>
> The invention of Group I does not make a contribution over the prior art, as evidenced by the prior art rejection set forth in the Office action of 189 August 2008.
>
> Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) of Group I are generic: 1, 3, 8-12 and 16.
>
> Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim [3] withdrawn from consideration as being directed to a nonelected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

DECISION

The petition filed under 37 CFR 1.144 on 23 January 2009 is **GRANTED-IN-PART**.

Claims 1, 3-12, 16-19, 25-37 are currently pending.

The lack of unity determination set forth on 28 June 2005 among the Groups I-IV has been maintained with the following modification that newly added claim 36 and 37 are placed in Groups I and III, respectively:

Group I, claims 1, 3-12, 16, 25 and 36 drawn to a bioadhesive pharmaceutical formulation comprising beta-limit dextrin
Group II, Claims 17-19 drawn to nutritional product comprising beta-limit dextrin
Group III, claims 26-29 and 37 drawn to a method of delivering an active agent formulation comprising beta-limit dextrin
Group IV, claims 30-35 drawn to a method of providing nutrition containing beta-limit dextrin

The request for rejoinder between the product (Group I) and process of using (Group III) is denied as premature, given that the product does not make a contribution over the prior art, as evidenced by the rejection under 35 U.S.C. 103(a). Should all claims to the elected invention become free of the prior art and should all claims to the process invention require all the limitations of the allowable product, the examiner should then consider rejoinder of Group III with Group I, per MPEP 821.04.

The election of species requirement made FINAL on 19 August 2008 amongst the species of buccal-melt and thin film is withdrawn.

With regard to Group I, the election of species requirement is set forth with the following modification:

Species (i) buccal melt, wafer, thin film, waxy starch, tablet formulations (because claims 4, 5, 7, 16 and 25 were already examined together on the merits and these limitations were specifically addressed in the prior art rejections)
Species (ii) aerosol powder of claim 6
Species (iii) lyophilized formulation of claim 36

Claims 1, 3, 8-12 and 16 of Group I are generic.

Because Claims 1, 3-5, 7-12, 16 and 25 read upon the elected/examined species of buccal melt, wafer, thin film, waxy starch tablets and deep freeze formulations of a bioadhesive pharmaceutical formulation comprising beta-limit dextrin, they will be examined together.

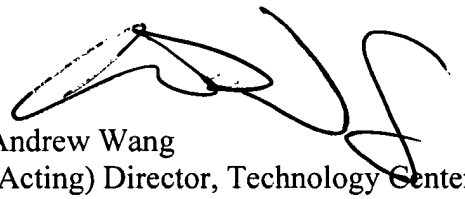
Claims 6 is withdrawn from consideration as being directed to non-elected species of aerosol powder, there being no allowable generic claim.

Claim 36 is withdrawn from consideration as being directed to non-elected species of lyophilized formulation, there being no allowable generic claim.

The application will be forwarded to the examiner to consider the papers filed 23 January 2009 and to prepare an Office action on claims 1, 3-5, 7-12, 16 and 25 and the elected/examined species of buccal melt, wafer, thin film, waxy starch and tablets formulations of a bioadhesive pharmaceutical formulation comprising beta-limit dextrin, consistent with this petition decision.

Any request for reconsideration of this decision should be filed within TWO (2) months of the mail date of this decision.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-272-8300.



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